REMARKS

This paper is in response to a *Non-Final Office Action* that issued in this case on 23 July 2010. Claims 1-3, 5, 6, 29-31, 33-44, and 46-54 are pending in the application and were rejected. The applicants respectfully request reconsideration in light of the foregoing amendments and the following comments.

Telephone Interview

A telephone interview was held on 4 November 2010 with Examiner Tanner Jocelin. The substance of the telephone interview was focused on the following topics:

(i) the *Affidavit ("Declaration")* filed on 13 May 2010;

(ii) the distinctions between the present invention and the cited references; and

(iii) suggested amendments that would further distinguish the present invention from the cited references.

In particular, suggested amendments were discussed, which included the clarification of the *"longitudinally extending member"* extending inward toward the center of the cross-section of the conduit.

In the *Examiner Interview Summary Record* filed on 12 November 2010, the Examiner stated that *"the suggested amendments appear to* ***distinguish*** *over the 'grooving' taught by Palmaz."* (*See*, continuation sheet of the *Examiner Interview Summary Record*.)

Voluntary Amendments to the Specification

The present application entered the United States under 35 USC § 371 from PCT application PCT/GB2004/002216. The applicants are submitting voluntary amendments to (i) the specification to include section headings and (ii) the Abstract to remove all reference numerals for the purpose of conforming to U.S. practice. The applicants respectfully submit that no new matter is entered with these amendments.

35 USC § 103 Rejection of Claims 1-3, 5, 6, 29-31, 33-44, and 46-53

Claims 1-3, 5, 6, 29-31, 33-44, and 46-53 were rejected under 35 USC § 103 as being obvious over the combination of EP 1254645 A1 (hereinafter "*Houston*") and US Patent No. 6,190,404 (hereinafter "*Palmaz*").

Additionally, claims 1-3, 5, 6, 29-31, 33-39, 46-49, and 53 were rejected under 35 USC § 103 as being obvious over the combination of FR 2657945 A (hereinafter "*Lee*") and Palmaz.

I. Claim 1 has been amended to more particularly point-out and distinctly claim the subject-matter that the applications regard as their invention.

The applicants respectfully submit that the various combinations of Houston, Palmaz, and Lee fail to teach or suggest at least one limitation recited in claim 1, as amended.

Independent claim 1, as amended, recites:

> **1.** An internal formation for a conduit, the formation comprising *a longitudinally extending member adapted to extend along an inside surface of at least a portion of the length of the conduit and projecting radially inwardly into the interior of the conduit*, the longitudinally extending member having an asymmetric profile in a direction transverse of the longitudinal axis of the member, wherein a first surface of the longitudinally extending member is at least partially directed towards an inlet of the conduit and a second surface of the longitudinally extending member is at least partially directed towards the outlet of the conduit and *wherein, at each radial cross-section of the conduit along which the longitudinally extending member extends, the angle that the first surface subtends with a diameter of the conduit extending through a portion of the profile of the longitudinally extending member closest to the radial centre of the conduit is less than 20º*, and wherein the internal formation effects spiral flow of a fluid flowing through the conduit.
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> ***(emphasis supplied)***

Houston and Palmaz, whether considered individually or in combination, fail to teach, suggest, or motivate what amended claim 1 recites — namely, an internal formation for a conduit, the formation comprising:

(i) a longitudinally extending member adapted to extend along an inside surface of at least a portion of the length of the conduit and projecting radially inwardly into the interior of the conduit;

(ii) wherein, at each radial cross-section of the conduit along which the longitudinally extending member extends, the angle that the first surface subtends with a diameter of the conduit extending through a portion of the profile of the longitudinally extending member closest to the radial centre of the conduit is less than 20º.

With respect to limitation (i) above, support for this amendment can be found at, *inter alia*, Figure 2; Figure 3; and pg. 5, ll. 6-pg. 6, ll. 9 of the originally filed specification.

With respect to limitation (ii) above, support for this amendment can be found at, *inter alia*, pg. 4, ll. 18-21 and pg. 5, ll. 6-pg. 6, ll. 9 of the originally filed specification.

In brief, independent claims 1 and 54 have been amended to further clarify that the *"longitudinal extending member"* is a *"ridge"* rather than a *"groove"* — to use the terminology of Houston.

II. At pg. 2, section 3 and section 4 of the present Office Action, the Office alleged that the present invention as defined in claim 1 is obvious over the combination of Houston and Palmaz. As further discussed below, the applicants respectfully disagree.

The applicants respectfully disagree because Houston and Palmaz each disclose a device that is significantly different from the device claimed in the present application.

In particular, Houston relates to blood flow tubing that has internal helical grooving and/or ridging in order to impart helical flow on blood passing through the tubing. (*See*, Houston at ¶0008 and ¶0009.)

In contrast, Palmaz discloses an intravascular stent that consists of at least one ***groove*** in order to promote the migration of endothelial cells. (*See*, Palmaz at *Abstract*.)

Accordingly, while Houston and Palmaz both describe intravascular devices that have internal grooves, the purpose of these grooves is entirely different. More specifically, and in accordance with Houston, the purpose is to impart helical flow on the blood passing through the blood flow tubing; whereas in Palmaz, the purpose of the grooving is to promote the migration of endothelial cells. Since the respective purposes of the grooves are different in each of the references, it would not have been obvious for a person skilled in the art to equate the grooves of Houston with the grooves of Palmaz, as alleged by the Office.

Even if a person skilled in the art were to combine the teachings of Houston and Palmaz (*which, as discussed above, a person skilled in the art would not be motivated to do so*), this combination would ultimately result in a device that extends beyond the scope of claim 1, as amended.

More specifically, Palmaz, at best, teaches the provision of grooves in the intravascular stent and not "*ridges*." In this regard, if a person skilled in the art were to

combine the teachings of Houston and Palmaz, then this skilled person would be inevitably selecting the ***"grooving" rather than the "ridging" from Houston***.

Indeed, it would be completely counter-intuitive for a person skilled in the art, based on the teaching of Palmaz, to select "ridging" since the purpose of the "grooves" in Palmaz is to promote the migration of endothelial cells. This is achieved because a groove renders the surface of the intravascular stent closer to the blood vessel in which the stent is located and, therefore, channels the cells within it.

In fact, a ridge would have an entirely ***opposite effect*** since it is further from the surface of the blood vessel and endothelial cells would be shed from a ridge rather than migrating through it.

Therefore, all aspects of the purpose of Palmaz would lead a person skilled in the art to provide a "*groove*" rather than a "*ridge*," which would thereby produce a device that is outside of the scope of claim 1, as amended.

III. In addition to being allowable for the reasons presented, the applicants submit that the Office's motivation to combine Houston and Palmaz is unreasonable.

More specifically, and at pg. 13, section 50 of the present Office action, the Office stated that *"since Palmaz et al. teaches several profile shapes, it would have been obvious that a skilled person would have pursued the known options within their technical grasp with a reasonable expectation that at least one would be successful."*

However, the logic behind the Office's above statement does not apply because the different shapes of "grooving" that are disclosed in Palmaz are for the purpose of promoting the migration of endothelial cells, ***rather than to impart helical flow on fluid passing through a blood vessel***.

Therefore, a person skilled in the art — when referring to Palmaz — would either (i) provide a device with grooving and, thereby, be outside the scope of amended claim 1, as discussed above or (ii) ignore the disclosure of Palmaz entirely.

The Office further goes on to state at pg. 13, section 50 of the present Office action that *"Houston discloses ridging and/or grooving that may be of any cross-sectional shape and size."* The applicants however submit that there is no direct and unambiguous disclosure in Houston of the cross-sectional shape of *"longitudinal extending member"* as recited in amended claim 1.

Lastly, the Office asserted at pg. 13, section 50 of the present Office action that, *"The various shapes and sizes [disclosed in Palmaz] would be obvious to apply to ridges as well."* However, for the reasons discussed above, this is not correct. Again, the applicants submit that Palmaz discloses various configurations for "grooving" because grooves will promote migration of endothelial cells. However, and as discussed above, ***a "ridge" would not have this technical effect so it would not be obvious to apply these shapes and sizes to ridges***.

In contrast to both Houston and Palmaz, what the present inventors have surprisingly found is that the provision of an internal formation for a conduit that comprises a longitudinally extending member — in particular, the asymmetric profile defined in amended claim 1 — provides good fluid rotation and a smooth, uniform fluid swirl pattern, whilst the fluid pressure is maintained throughout the length of the conduit. In this regard, it would not have been obvious from the disclosure of Houston and Palmaz to achieve this technical effect by providing an internal formation of a conduit as defined in amended claim 1.

For at least the reasons discussed above, Houston and Palmaz fail to teach, suggest, or motivate the limitations at issue recited in amended claim 1. As a consequence, amended claim 1 is allowable over Houston and Palmaz, whether considered individually or in combination.

IV. At pg. 8, section 30 and section 31 of the present Office Action, the Office further alleged that the present invention as defined in claim 1 is obvious over the combination of Lee and Palmaz. The applicants respectfully disagree, as further discussed below.

However, it would not have been obvious to a person skilled in the art to combine Lee with Palmaz in order to arrive at the present invention for similar reasons as set-out above with respect to the combination of Houston and Palmaz. Indeed, Lee is even less relevant than Houston, as further discussed below.

Lee, at best, only makes reference to helical protuberances. But there is no reference whatsoever to helical grooves in Lee. (*See*, Lee at first paragraph and fourth paragraph.)

Furthermore, Lee relates to a different technical field from Palmaz. As stated in the third paragraph of Lee, the purpose of the *"pipe"* in Lee is to solve the problem that when fluid drops vertically in a pipe, the noise generated by the slow flow, the shocks in the fluid

itself, and the regular shocks of friction of fluid in the surface of the pipe are propagated towards the outer surface of the pipe. Thus, as explained in the fourth paragraph, Lee's invention concerns a "pipe" that dissipates the noise produced.

Lee's invention achieves this by the provision of a layer of foam material between inner and outer layers of synthetic resin. This is particularly illustrated in, for example, Figure 1 of Lee in which a foam material is sandwiched between an inner layer (3) and an outer layer (1). Thus, it is implicit that the technical field of the device in Lee is one of domestic and industrial transportation of fluids. For at least this reason, Lee is not in the medical field because the problem of the noisy flow of liquid through blood vessels ***does not arise and a person skilled in the art would not be motivated to search the technical field of Lee to cure the deficiencies of Houston and Palmaz***.

v. Furthermore, the technical solution provided by Lee — namely, the replacement of "pipes" with thicker insulated pipes — simply ***would not be appropriate in the medical field***. As explained above, the technical field of Palmaz is an intravascular stent which is clearly an entirely different technical field from Lee. For at least this reason, it would not be obvious for a person skilled in the art to combine the teachings of Lee and Palmaz in the fashion suggested by the Office.

Lastly, and as previously discussed, even if a person skilled in the art were to combine Lee and Palmaz, there is the added technical difficulty of resolving the inconsistency between the two references.

More specifically, Lee discloses a "pipe" with ridges (*See*, the helical protuberances (4) in Figure 1 of Lee); whereas, Palmaz discloses a stent with "grooves." There is no teaching, suggestion, or motivation in both Lee and Palmaz regarding how to reconcile this inconsistency since the purpose of the respective devices of each reference are entirely different (*i.e.,* the purpose being to reduce noise of fluid flow through pipes in Lee and the promotion of migration of endothelial cells in blood vessels in Palmaz). That is, there is no motivation in Lee to enable a person skilled in the art to resolve this technical inconsistency and deficiency of Palmaz, and vice versa.

For at least the reasons discussed above, Lee and Palmaz fail to teach, suggest, or motivate the limitations at issue recited in amended claim 1. As a consequence, amended claim 1 is also allowable over Lee and Palmaz, whether considered individually or in combination.

Since claims 2, 3, 5, 6, 29-31, 33-44, and 46-53 are dependent on amended claim 1, and because amended claim 1 is believed to be allowable for the reasons presented, these dependent claims are likewise allowable. Moreover, the recitation of additional patentable features recited in these dependent claims provides an additional basis for patentability.

35 USC § 103 Rejection of Claim 54

Claim 54 was rejected under 35 USC § 103 as being obvious over the combination of Houston and Palmaz. Additionally, claim 54 was rejected under 35 USC § 103 as being obvious over the combination of Lee and Palmaz.

Claim 54 has been amended to more particularly point-out and distinctly claim the subject-matter that the applications regard as their invention.

The applicants respectfully submit that the various combinations of Houston, Palmaz, and Lee fail to teach or suggest at least one limitation recited in claim 54, as amended.

Independent claim 54, as amended, recites:

> **1.** An internal formation for a conduit, the formation comprising *a longitudinally extending member adapted to extend along an inside surface of at least a portion of the length of the conduit and projecting radially inwardly into the interior of the conduit*, the longitudinally extending member having an asymmetric profile in a direction transverse of the longitudinal axis of the member, wherein a first surface of the longitudinally extending member is at least partially directed towards an inlet of the conduit and a second surface of the longitudinally extending member is at least partially directed towards an outlet of the conduit, and wherein the first and second surfaces extend from the inside surface of the conduit towards each other and are coupled together at an apex or by a curved third surface, and *wherein, at each radial cross-section of the conduit along which the longitudinally extending member extends the angle that the first surface subtends with a diameter of the conduit extending through a portion of the profile of the longitudinally extending member closest to the radial centre of the conduit is less than 20º*, and wherein the internal formation effects spiral flow of a fluid flowing through the conduit.
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> ***(emphasis supplied)***

Claim 54, as amended, is allowable over the various combinations of Houston, Palmaz, and Lee for essentially the same reasons as amended claim 1. In particular, these

references, whether considered individually or in any combination, fail to teach, suggest, or motivate what amended claim 54 recites — namely, an internal formation for a conduit, the formation comprising:

(i) a longitudinally extending member adapted to extend along an inside surface of at least a portion of the length of the conduit and projecting radially inwardly into the interior of the conduit;

(ii) wherein, at each radial cross-section of the conduit along which the longitudinally extending member extends the angle that the first surface subtends with a diameter of the conduit extending through a portion of the profile of the longitudinally extending member closest to the radial centre of the conduit is less than 20º.

For at least the reasons discussed above with respect to amended claim 1, amended claim 54 is also allowable over the art of record.

No Waiver

All of the applicants' arguments are without prejudice or disclaimer. The applicants reserve the right to discuss the distinctions between the applied art and the claims in a later response or on Appeal, if appropriate. By not responding to additional statements made by the Office, the applicants do not acquiesce to the Office's additional statements. The distinctions discussed by the applicants above are sufficient to overcome the rejections.

Request for Reconsideration Pursuant to 37 § CFR 1.111

Having responded to each and every ground for objection and rejection in the last Office action, applicants respectfully request reconsideration of the instant application pursuant to 37 CFR § 1.111 and request that the Examiner allow all of the pending claims and pass the application to issue.

If there are remaining issues, the applicants respectfully request that Examiner telephone the applicants' attorney so that those issues can be resolved as quickly as possible.

Respectfully,
John Graeme Houston et al.

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